

MedDRA Literature Commentary

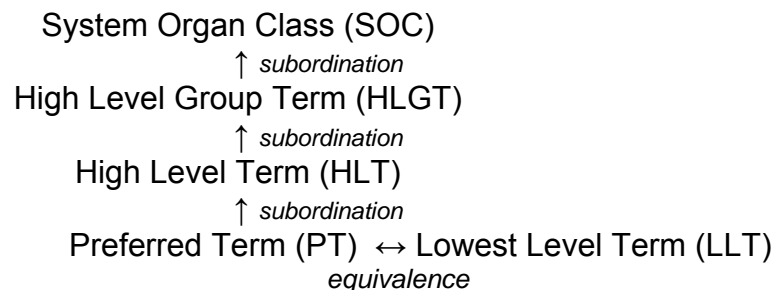
Subject of commentary:

Merrill, G. The MedDRA Paradox. AMIA 2008 Symposium Proceedings, 470 – 474

Commentary: The argument of this interesting article is that Lowest Level Terms (LLTs) are not subordinate to Preferred Terms (PTs) in MedDRA but – from an ontologic perspective – are equivalent (hence, the “paradox”).

The author summarizes the paradox early in the article as follows: “Even though all of the LLTs linked to a PT are equivalent to one another – and this includes the PT itself – and even though they refer to the same medical concept, still, section 3.1 of [the MedDRA Introductory Guide, v10.1] informs us that LLTs are *subordinate* to their PT and occupy a distinct level in the MedDRA structural hierarchy. In a particularly confusing twist, it is further asserted that the LLT that is *identical* to the PT is also *subordinate* to it, that in that case the PT is the “parent” of the LLT, and that although the LLT and PT ‘have the same MedDRA code’ (they are after all, *identical* – they are the same term), they ‘appear at both levels’. Thus it seems that the PT is subordinate to itself, which is not possible.”

In other words, the hierarchy of MedDRA – according to this author – should be represented as follows:



The author argues that the current depiction of LLTs as described in the MedDRA Introductory Guide may cause an issue in informatics contexts by encouraging the view that LLTs are less general/more specific than PTs rather than equivalent to them. In particular, the author goes on to cite a Web page describing MedDRA (Version 9.0) in the Unified Medical Language System (UMLS) where he notes “questions” (i.e., phrases followed by question marks) interpreted as confusion on the part of the page author about the meaning of the LLT and PT relationships in MedDRA. The MSSO interprets this page with its question marks as a format anomaly rather than a series of questions (http://gforge.nci.nih.gov/docman/view.php/53/2278/MedDRA_Source_Information.html). We invite the reader to decide for herself/himself.

The MSSO concedes that the author's argument may have some technical merit, but additional points should be borne in mind before we conclude that MedDRA is seriously flawed by this "paradox":

- The points raised by the author may be of interest to ontologists but have little impact on the general users of MedDRA for the purpose for which it was designed (regulatory reporting)
- From the MSSO's point of view, after a decade of MedDRA's use in the biopharmaceutical industry, the "paradox" has not led to any adverse consequences
- The author's argument is somewhat philosophical, and the practical application of his revised way of depicting the MedDRA hierarchy appears to be lacking
- MedDRA was not intended to be a taxonomy, and the particular way that LLTs relate to PTs was meant to aid in consistency of coding events

The MSSO appreciates that the author sees this as an issue of MedDRA's use in the "broader informatics context" and in conjunction with other thesauri, vocabularies, and ontologies. Certainly, challenges of interoperability between such entities are not restricted to MedDRA and its "paradoxical" hierarchy; in other words, trying to map or relate diverse terminologies/ontologies to one another is not always a simple task.¹ We applaud the author's attempt to explain the LLT-PT "paradox", but we do not see it as hampering MedDRA's current utility or future development.

Summary:

This article – written from an ontology perspective – identifies a purported "paradox" in the way that LLTs are depicted as subordinate to their parent PTs (the author argues that LLTs are instead equivalent to PTs). Although the MSSO understands and appreciates the explanation, for now, the practical consequences of this "paradox" appear minimal.

References:

1. Richesson RL, et al, Heterogeneous but "standard" coding systems for adverse events: Issues in achieving interoperability between apples and oranges, *Contemp Clin Trials* (2008), doi:10.1016/j.cct.2008.02.004